

REMARKS

Reconsideration of the above-identified application in view of the amendments above and the remarks following is respectfully requested.

Claims 1-52 are in this case. Claims 1, 7, 8, 10, 11, 13, 19, 20, 22-24, 26-29, 32-35, 38, 39 and 49-52 have been rejected under § 102(b). Claims 2-6, 9, 12, 14-18, 21, 25, 30, 31 and 36-48 have been rejected under § 103(a). Claims 1, 2, 11, 13, 14, 24, 26, 32 and 46 have also been objected to. Independent claims 1 and 13, and dependent claims 2-5, 14-17, 22 and 24, have now been amended. Claims 26-52 have been canceled without prejudice.

Interview Summary

Reference is made to a telephone interview held in two parts on July 13 and July 14, 2006, between Examiner Paul Smith of the PTO and Daniel Michaels, speaking under the auspices of Dr. Mark Friedman, for the Applicant. The interview related to the § 102(b) rejections of independent claims 1 and 13 over the Palmer ('242) reference. No agreement was reached as to the allowability of any claim.

The Applicant first expressed an intention to cancel claims 26-52 without prejudice in order to simplify the issues before the Examiner and expedite the prosecution.

Regarding independent claims 1 and 13, the Applicant pointed out, and the Examiner agreed, that the motion of the device proposed by Palmer and that of the present invention are significantly different. Specifically, the motion of the needles of Palmer is essentially perpendicular to the skin surface whereas that of the present invention includes a non-zero component parallel to the surface of the skin. The Examiner stated, however, that the skin stretching device of Palmer causes relative

movement of part of the skin underlying the microneedles in a direction parallel to the skin surface. As a result, the Examiner considered that the current claim language did not sufficiently clearly express the distinctions in structure and operation of the present invention over the Palmer reference.

The Applicant agreed to submit an amendment to the claim language for further consideration by the Examiner.

The Applicant thanks the Examiner for his generous allocation of time and helpfulness in this matter.

Claim Objections

The Examiner has objected to claims 1, 2, 11, 13, 14, 24, 26, 32 and 46 for inconsistent use of the phrases “said surface”, “said planar surface” and “said substantially planar surface.”

The claims in question have now been amended to address the issue raised by the Examiner. Specifically, care has now been taken to use the full phrase “substantially planar surface” throughout the claims. The Applicant believes that the claims are now free from the deficiencies identified by the Examiner.

§ 102(b) & § 103(a) Rejections – Claims 26-52

The Examiner has rejected claims 26-29, 32-35 and 49-52 under § 102(b) as being anticipated by Palmer. The Examiner has also rejected claims 38 and 39 under § 102(b) as being anticipated by Roser. The Examiner has further rejected claims 30, 36, 40 and 46-48 under § 103(a) as unpatentable over Palmer in view of Peterson. The Examiner has still further rejected claims 31 and 37 under § 103(a) as unpatentable over Palmer in view of Eppstein and Paul. Finally, the Examiner has rejected claims

41-45 under § 103(a) as unpatentable over Roser. The Examiner's rejections are respectfully traversed.

While continuing to traverse the Examiner's rejections, the Applicant has chosen, in order to expedite the prosecution, to cancel claims 26-52 without prejudice, thereby rendering moot the above-mentioned rejections of these claims. The Applicant reserves the right to submit the canceled claims in the context of a continuation application for further consideration in due course.

§ 102(b) & § 103(a) Rejections – Claims 1-25

The Examiner has rejected claims 1, 7, 8, 10, 11, 13, 19, 20 and 22-24 under § 102(b) as being anticipated by Palmer. The Examiner has further rejected claims 2-6 and 14-18 under § 103(a) as unpatentable over Palmer in view of Tobinaga. The Examiner has still further rejected claims 9 and 21 under § 103(a) as unpatentable over Palmer in view of Peterson. Finally, the Examiner has still further rejected claims 12 and 25 under § 103(a) as unpatentable over Palmer in view of Eppstein and Paul. The Examiner's rejections are respectfully traversed.

The Palmer reference discloses a microneedle fluid delivery device which includes a skin stretching device in the form of a conical shield which outwardly stretches the skin symmetrically around the intended region of microneedle penetration.

In contrast, the device and method of the present invention implement a sliding insertion technique in which microneedles are brought into contact with the skin and then moved in a sliding motion which has a component parallel to the skin surface so as to enhance penetration of the microneedles through the skin. This technique is clearly neither taught nor in any way suggested by the Palmer reference considered alone or in combination with any other reference of record.

While continuing to traverse the Examiner's rejections, the Applicant has, in order to expedite the prosecution, chosen to amend independent claims 1 and 13 in order to clarify and emphasize the crucial distinctions between the device and method of the present invention and those of the Palmer patent cited by the Examiner. Specifically, claim 1 has been amended to clarify that the abutment member is configured to anchor a region of the biological barrier so as to oppose movement of the biological barrier parallel to a surface of the biological barrier, and further that the displacement mechanism defines a path of movement of the fluid transport configuration such that the microneedles move in contact with the biological barrier in a direction having a non-zero component parallel to the surface of the biological barrier.

Independent claim 13 has also been amended to clarify that the fluid transport configuration is displaced so that said microneedles move in contact with said biological barrier along a path of movement having a non-zero component parallel to said substantially planar surface.

Support for these amendments can be found in the specification. Specifically, support for the anchoring of a region of the biological barrier against in-plane movement may be found on page 10, lines 20-22.

Amended independent claims 1 and 13 now feature language which makes it absolutely clear that the device and method of the present invention implement motion of the microneedles in contact with the biological barrier in a direction having a non-zero component parallel to the surface of the biological barrier. The Applicant believes that the amendment of the claims completely overcomes the Examiner's rejections on § 102(b) and § 103(a) grounds.

In view of the above amendments and remarks it is respectfully submitted that independent claims 1 and 13, and hence also dependent claims 2-12 and 14-25, are in condition for allowance. Prompt notice of allowance is respectfully and earnestly solicited.

Respectfully submitted,



Mark M. Friedman
Attorney for Applicant
Registration No. 33,883

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